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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,031	01/11/2002	Stephen F. Badylak	3220-69262	9094

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
05/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/044,031	BADYLAK ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9-11 and 16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, 9-11, and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Information Disclosure Statement

The information disclosure statement filed April 2, 2010 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copies of the references struck from the PTO/SB/08a form have not been considered because a copy could not be found in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Abraham et al (US 5,993,844). Abraham anticipates the claim language where Abraham states that the final product is “endotoxin free” such that it is within the claimed range of less than 12 endotoxin units per gram; see column 8, line 55 to column 9, line 13 and column 4, line 49 to column 5, line 6.

The effective filing date of the present claims 4-6, 9, 10, and 16-20 is August 22,

1997 because support for the range of "an endotoxin level of less than 12 endotoxin units per gram" is not present in either provisional application 60/024,693 or 60/024,542. Rather, the apparently narrower range of "essentially zero bioburden level" is supported in these applications.

In addition, present claims 4-6 do not have support from the provisional applications because there is no clear mention of the number of colony forming units thereof. Additionally, claim 9 has features that are not supported by the provisional applications.

However, claims 1 and 11 now have an effective filing date of August 23, 1996 because the rand of less than 5 endotoxin units per gram has support from provisional application 60/024,542 on page 7, lines 7-23 of the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-10 and 16-20 are rejected under 35 U.S.C. 102(e) as anticipated by Abraham et al (US 5,993,844) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abraham et al (US 5,993,844) alone.

Regarding claims 9-10 and 16-20, Abraham reasonably discloses the claimed invention as explained *supra* in the Section 102(e) rejection therewith, but fails to clearly

disclose the product-by-process steps recited in the claims; see MPEP 2113 that is incorporated herein by reference. However, the claimed product appears to be identical to the product disclosed by Abraham such that the claimed invention is considered anticipated thereby.

Alternatively, since the present claims contain product-by-process limitations, it is not explicitly clear that the product resulting from these process steps results in a product that is identical or substantially identical to that of Abraham. However, even if the process steps result in a different product from that of Abraham, the Examiner asserts that the difference is slight such that the claimed invention would have been considered at least obvious in view of Abraham alone.

With regard to claim 16, the tela submucosa claimed is inherently present in the tissue of Abraham since the same tissue as claimed is purified by Abraham.

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yannas et al (US 4,060,081) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yannas et al (US 4,060,081) alone. Yannas anticipates the claim language where purified collagen is used to make the graft so it is indistinguishable from collagen of other sources in that all the other source components have been removed. The purified structure is inherently free of endotoxins because all endotoxins have been removed via the process of purification; see the abstract and example 1 on columns 14 and 15, particularly the first two paragraphs of Example 1; see MPEP 2113 that is incorporated herein by reference thereto.

Alternatively, if there is a difference in the collagen due to the source utilized to make it that difference is so slight that it would have been considered *prima facie* obvious to an ordinary artisan viewing Yannas purified collagen.

Interference Sought

It is noted that the Applicants are seeking to provoke an interference with another assignee of the same subject matter. The request for interference filed March 14, 2008 is acknowledged. However, examination of this application has not been completed as required by 37 CFR 41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

Response to Arguments

Applicant's arguments filed February 5, 2010 have been fully considered but they are not persuasive.

The Applicants argue that the claim language pertaining to colony forming units is not disclosed by Abraham; see page 9 of the response filed February 5, 2010. However, since the specification indicates that colony forming units are living microorganisms (see page 7, lines 1-3) and since Abraham teaches sterilization to the point that no endotoxins are present, the Examiner asserts that it is clearly inherent that all living organisms are not present. It is noted that there is no special definition for colony-forming units (because the definition is exemplary and illustrative) so this terminology is interpreted broadly to limit the presence of microorganisms. Sterile, as

set forth by Abraham, is understood to mean free of microorganisms. For this reason, the claim language is considered fully met.

An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.' see *Teleflex, Inc. v. Ficosa No. Am. Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002).

In response to the traversal of the claims 9, 10, and 16-20 rejection (see page 10 of the response), the Examiner reminds the Applicant that he is under a lesser burden when product claims are set forth with respect to the process utilized to make the product. In the present situation, it is not clear that the process steps would result in a different product because Abraham discloses a sterile material that is free of endotoxins. For this reason, the rejection has been maintained.

With respect to the traversal of the Yannas rejection of claim 1 and 11, the Examiner asserts that the process of treating with lime, 0.3% propionic acid, 0.1% benzoic acid (for 4 hours), then grinding and centrifuging, then treating with 0.05 M acetic acid and 0.2 M dihydrogen phosphate, then homogenizing the dispersion would inherently result in no endotoxins or colony forming units as claimed. It would clearly stand to reason to one of ordinary skill that the steps taken to purify collagen would inherently result in a product that is identical or at least substantially identical to the claimed product. For this reason, the rejection has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774